



Decree No. (1) of 2015
On amendments to some items and official forms of Decree No (1) of 2010 and the
addition of some controls

First: Amendments to some items of Decree No (1) of 2010

Serial No.	Item Number	Item text before amendment	Item text after amendment
1	First – (1) – (f)	Ensuring that the application shall mention the license applicant address in which he can receive correspondence in a way that ensures the arrival of the papers and their entries in the register by means of a registered letter of recorded delivery.	Ensuring that the application shall mention the license applicant address in which he can receive correspondence in a way that ensures the arrival of the papers and their entries in the register by means of a registered letter of recorded delivery. The license applicant shall notify the Pharmacy Department of his new correspondence address in the case of changing his address to which correspondence is made.
2	First – (2) – (1)	An application with due stamp duties and complete data for opening a pharmaceutical institution shall be delivered to the pharmacist with an ID card of the Pharmacists' Syndicate or to a first-degree relative with a special power of attorney (the application data must be fully completed in front of the pharmacy inspector in the Directorate).	An application with due stamp duties and complete data for opening a pharmaceutical institution shall be delivered to the pharmacist with an ID card of the Pharmacists' Syndicate or to his agent with a power of attorney showing the mandated procedure, and a copy of the general power of attorney and a copy of the identity verification of the agent shall be kept in the license file, provided that the original copy of the special power of attorney is withdrawn (the application data must be fully completed in front of the pharmacy inspector in the Directorate, taking into account the identification of the address of the pharmacy to be licensed, and the

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3	Fourth - (1)	Any of the six basic documents required for licensing which are referred to earlier in item First /2 shall not be attached.	address of the license applicant to which correspondence is made.). Any of the six basic documents required for licensing which are referred to earlier in item First /2 shall not be attached, except for a copy of the license to practice the profession or a copy of ID card of the General Syndicate (provided that they shall be submitted later among the other required documents).
4	Seventh Inspections	- Inspection shall be conducted by a three-inspector committee, provided that one of them is experienced in the licensing procedure. - The identity of the license applicant or his agent who has a special power of attorney must be verified and a copy of the power of attorney and a copy of the identity verification of the agent shall be kept in the file.	- Inspection shall be conducted by a three-inspector committee, provided that one of them is experienced in the licensing procedure and that the license applicant or his agent shall be present without prejudice to the provisions of item First - (2) - (1) pertaining to the procedures of the agent.
5	Seventh Inspections - Note - (2)	The license applicant or his agent must be present when inspection is being conducted.	When inspection is being conducted, the license applicant or his agent must be present without prejudice to the provisions of item First / (2) - / (1) pertaining to the procedures of the agent.
6	Seventh Inspections - (A- First Inspection) - Note	If the license applicant submits a request stating that it is not possible to increase the area of the pharmacy or that one of the prescribed health requirements	If the license applicant submits a request stating that one of the prescribed health requirements cannot be fulfilled, the license application shall be reserved before its grace period expires.

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		cannot be fulfilled, the license application shall be reserved before its grace period expires.	
7	Seventh – Inspections – (A- First Inspection) – (1)	That the shop to be licensed shall be identifiable by three walls, a door and a ceiling.	The shop to be licensed shall be identifiable by three walls, a ceiling, and an entrance opening to the property.
8	Seventh – Inspections – (A- First Inspection) – Notes – (1) – (B)	The layout of the shop to be licensed is fundamentally different from the submitted engineering drawing, unless difference is designated to increase the area to be 40 m, as provided by Resolution No. (380) of 2009.	The layout of the shop to be licensed is fundamentally different from the submitted engineering drawing in a way that changes the boundaries of the property to be licensed.
9	Seventh – Inspections – (A- First Inspection) – Notes – (1) – (D)	If the place to be licensed is not identifiable by three walls, a door and a ceiling	If the place to be licensed is not identifiable by three walls, a ceiling, and an entrance opening to the property
10	Seventh – Inspections – (A- First Inspection) – Notes – (2)	The area of a pharmacy may be divided into two floors based on the decision of a committee formed by the Central Administration for Pharmaceutical Affairs, provided that the area of the ground floor is not less than 25 m, and the rest of the area is completed in the upper floor.	A pharmacy on two floors may be licensed, provided that the area of the ground floor is not less than 25 m, taking into account the fulfillment of the requirement of height (260 cm) in each floor, provided that the ground floor is connected to the next floor with an internal staircase, and no floor shall be connected to any other activity or to residence place.
11	Seventh – Inspections – Second Inspection – (9)	The license shall be offered after signing an acknowledgment of receiving the license and an undertaking to open the pharmacy within	The license shall be offered after signing an acknowledgment of receiving the license and an undertaking to open the pharmacy within six months from the date of issuing the license, provided that



		<p>six months from the date of issuing the license, provided that the license is handed to the applicant or to his agent with a special power of attorney where the receipt of the pharmacy license shall be stated therein.</p>	<p>the license is handed to the applicant or to his agent with a power of attorney where the receipt of the pharmacy license shall be explicitly stated therein, without prejudice to the provisions of item First - (2) - (1) pertaining to the procedures of the agent.</p>
12	Eight - (1)	<p>For licensing applications submitted as from 1/2/2010, the net floor area of a public or a private pharmacy shall not be less than 40 square meters and that of warehouses and drug stores shall not be less than five hundred square meters.</p>	<p>The area of a public or a private pharmacy shall not be less than 25.</p>
13	Eight - (5)	<p>The building must be constructed from modern building materials that comply with the Egyptian standard specifications. It is sufficient to have a building permit issued by the neighborhood municipality or to have, in the case of squatter areas, a certificate that no removal decision has been issued. The walls must be covered with whatsoever washable materials that inhibit bacteria growth. There are no requirements regarding a certain wall-covering material or a certain painting.</p>	<p>The building must be constructed from modern building materials that comply with the Egyptian standard specifications. It is sufficient to have a building permit issued by the neighborhood municipality along with a statement therefrom in accordance with the attached form (Amended Appendix 6), or a certificate from the neighborhood municipality stating that no removal decision has been issued and that the building is structurally safe in the case of squatter areas. The walls must be covered with whatsoever washable materials that inhibit bacteria growth. There are no requirements regarding a certain wall-covering material or a certain painting.</p>

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14	Eight – (10)	Water resource must be obtained from the public water supply through a pharmacy-specific water meter.	Water resource must be obtained from the public water supply through a pharmacy-specific water meter. In the event that meters are not available in the water company for installation, the applicant may submit an official certificate issued by the competent water company stating this fact. In addition, the shop to be licensed shall be provided with an independent sub-connection that supplies the shop with water on a regular and continuous basis, provided that the applicant shall officially undertake to install a pharmacy-specific water meter whenever available in the water company. Pharmaceutical inspection must follow up this situation.
15	Eight – (12)	A flat-bottomed sink that is made of china or cast-iron.	A flat-bottomed sink that is made of china, cast iron, or whatever.
16	Eight – (14)	If there is a bathroom, it is required to have therein a window giving on to a skylight or a street. An extractor may be used, and the toilet must drain into private manholes that drain into public sewers.	If there is a bathroom, it is required to have therein a window giving on to a skylight or a street and it is permissible to use an extractor. In the event that it is not possible to open a window on a skylight or a street, that window may be replaced by an extractor connected to a pipe that ends to a skylight or to a street in a way that allows ventilation. The toilet must drain into a private manhole that drains into public sewers.
17	Eight – (15)	For building overhanging eaves to be approved in the area of the pharmaceutical	For building overhanging eaves to be approved in the area of the pharmaceutical institution, a license of

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		institution, a permanent license of the building eaves must be obtained from the neighborhood municipality to which the pharmaceutical institution belongs.	the building eaves must be obtained from the neighborhood municipality to which the pharmaceutical institution belongs. After the issuance of the license, the owner is obligated to provide evidence of renewing the license of the eaves.
18	Eight – (16) – (C)	The height of the wall under the attic is not less than two meters and it is located in the last quarter of the pharmacy.	The height of the wall under the attic is not less than two meters and its area shall not exceed one third of the area of the pharmacy.
19	Eighth: Cases which must be referred to the General Administration for Pharmaceutical Affairs and which must be adjudicated by a committee to be formed by the said administration.	Cases which must be referred to the General Administration for Pharmaceutical Affairs and which must be adjudicated by a committee to be formed by the said administration.	Cases which must be referred to the General Administration of Pharmaceutical Affairs at the Directorate of Pharmaceutical Affairs and which must be adjudicated by a committee to be formed by the said administration.
20	Ninth – (1)	A certificate from the Central Administration for Pharmaceutical Affairs specifying the pharmacist's stance with regard to government work and government-mandated internship (which is valid of three months).	A certificate from the Central Administration for Pharmaceutical Affairs specifying the pharmacist's stance with regard to government work and government-mandated internship (which is valid of sixty days).
21	Ninth – (2)	A certificate from the Central Administration for Pharmaceutical Affairs demonstrating the	A certificate from the Central Administration for Pharmaceutical Affairs demonstrating the pharmacist's ownership in public pharmacies or his

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		pharmacist's ownership in public pharmacies or his joint ownership in them (which is valid for three months).	share in their ownership (which is valid for sixty days).
22	Ninth – (4)	A letter from neighborhood municipality to which the pharmacy belongs stating that the shop to be licensed as a pharmacy is not an apartment or a garage.	A letter from the neighborhood municipality to which the pharmacy belongs in accordance with the attached form (Amended Appendix 6).
23	Ninth – (6)	A document proving the existence of a permanent source of electricity (electricity receipt – a purchase invoice for an electric generator).	A proof that there is a permanent source of electricity (a receipt of electricity consumption with a permanent meter for the property to be licensed, or a certificate from an electricity company stating that electric current has been extended for the property to be licensed at a permanent and continuous basis until a permanent meter is installed).
24	Ninth – (7)	A notarized original lease or title of the property to be licensed. The lease term may not be less than five years; the lease or the title shall be perused and a copy thereof shall be kept after being signed by a department inspector as a certified true copy.	A notarized original lease or title of the property to be licensed. The lease term may not be less than five years; the lease or the title shall be perused and a copy thereof shall be kept after being signed by a department inspector as a certified true copy. Contracts concluded with units affiliated to the State's administrative apparatus in accordance with the Tenders and Auctions Law No. (89) of 1998 shall be excluded from the five-year lease term, provided that it shall not be less than three years.

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Second: Amendments to some appendices of Decree No. (1) of 2010:

The following appendices have been amended as follows:-

{1} Appendix No. (1):-

Governorate
Directorate of Health Affairs
Medical District
Pharmacy Department

A license application for a public or a private pharmacy

Distinguished Dr. /
Greetings; to begin with,

I should be grateful if you would agree to issue a pharmacy license for me; my personal details are as follows:

Name and surname of the license-requesting applicant
Date of birth Nationality.....
Residential address..... Phone number
Mobile number

Names and addresses of pharmacies that I own or have a share therein:-

- Pharmacy Name Pharmacy Address
- Pharmacy Name Pharmacy Address
The trade name of the pharmacy to be licensed
Address of the pharmacy to be licensed
The name of the owner of the property in which the pharmacy to be licensed shall be located
License type of the pharmacy to be licensed: a public pharmacy / a private pharmacy
Number of a receipt evidencing payment of examination fees.....
Pharmacist registration number in the records of the Ministry of Health Registration Date / /
Pharmacist registration number in the General Syndicate Registration Date / /

Executed on / /

Please accept best regards.

License- requesting applicant's name

Pharmacist/

Signature :.....

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Receipt

By signing below, I hereby acknowledge that I
have received the application submitted by Mr.
concerning and that the application fulfills all the
requirements for obtaining the service (documents - fees).
The application is registered under No. on / / 20
The date specified for completion of the service / / 20

Signature of the authorized employee
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Rules governing the procedures for obtaining the service

Pursuant to the Prime Minister's Decree No. (4248) of 1998 regarding facilitating citizens' access to public services, including the service of obtaining a license for a public pharmacy in the Ministry of Health, the concerned administrative authorities shall provide the service in accordance with the content of this form, issued on // as a result of cooperation between the Central Agency for Organization and Administration, the Ministry of Health and Population and the governorates, that specifies the documents, papers and charges required to obtain the service, sets scheduled deadlines for its completion, ensures declaring the opinion on the application submitted for obtaining the service, and states that any violation of these rules shall entail the assumption of liability, as follows:-

First: Required documents and papers:

Documents that shall be sent by means of registered mail with recorded delivery and be attached to the pharmacy license application available free of charge in the pharmacy departments of the Directorates of Health Affairs and Medical Districts. They are as follows: -

- A copy of the national ID card or passport. -Birth certificate or an official extract therefrom (original).
- A valid conviction-free criminal status record, issued to be submitted to the Department of Pharmacy (original).
- Receipt of payment of the examination fees in the name of the Department of Pharmacy.
- Three copies of the engineering layout of the pharmacy to be licensed (with complete stamp duties and approved by an authorized syndicate engineer).

Other documents required for licensing that shall be submitted after the first inspection:

- A license to practice the profession of pharmacy, complete with stamp duties and a copy of the Pharmacists' Syndicate ID card or the most recent payment receipt of the Syndicate subscription.
- A certificate complete with stamp duties from the Central Administration for Pharmaceutical Affairs at the Ministry of Health stating that the applicant pharmacist has no ownership or share in more than two pharmacies.
- A certificate with complete stamp duties issued from the Central Administration for Pharmaceutical Affairs at the Ministry of Health demonstrating the pharmacist's stance with regard to work for government or the public sector, and stating that after his graduation, he has spent more than a year in practicing the profession of pharmacy in a governmental or a private institution (unless pharmacy ownership has been transferred to him by inheritance or bequest).
- A certificate of approval for the pharmacy trade name from the subsidiary Pharmacists' Syndicate.
- A certificate stating that the license requesting applicant pharmacist has not received any disciplinary actions or convictions, and that he is still registered in the General Syndicate's roll.
- A copy of the title of the property to be licensed or a copy of the lease whose term is not less than five years- either the title or the lease shall be notarized by the real estate registry. (The original contract shall be submitted only for perusal)
- A document stating that water source is extended from the public water supply to the property to be licensed through a commercial meter.

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- A document stating that a permanent source of electric current is extended to the property to be licensed with a commercial meter.

- In the case of licensing a private pharmacy: - The aforementioned documents (except for the two certificates of the Central Administration for Pharmaceutical Affairs at the Ministry of Health, and the title or the lease) are submitted in addition to the following documents: -

- An authorization from the administration of the hospital in which the pharmacy to be licensed shall be located for a representative to carry out the pharmacy licensing procedures.

- A certified true copy of the hospital license approved by the Administration of Free Treatment.

Second: Due fees required for obtaining the service:

An examination fee of LE 5 (five Egyptian pounds) shall be paid to the treasury via a receipt of 5 Egyptian pounds or a money order (under Article 12 of Law No. (127) of 1955 on Pharmacy Profession Practice).

A specific tax of LE 3 (three Egyptian pounds) shall be paid for the license (under Article 89 of Law No. 111 of (1980) on Stamp Duty and its amendments).

A resource development fee of 10 piasters (ten piasters) (under Law No. 147 of (1984) and its amendments).

Note: In the event of multiple copies or duplicates of the license that the Directorate shall keep for work purposes, the applicant shall only bear the tax due on only one of those copies or duplicates.

Third: Scheduled deadlines for the completion of the service:

- The competent department shall conduct inspection procedures and inform the license applicant of its opinion within a period of no later than thirty days from the date of the application entry in the register.

The failure of the administration to inform the license applicant of its opinion after the lapse of the scheduled deadline (thirty days) shall be considered as an approval for the location of the pharmacy.

- The license shall be issued within thirty days of the inspection date in the event that the prescribed health requirements and documents are fulfilled.

In the event that the health requirements of the pharmacy to be licensed are not fulfilled, the applicant must be given an initial grace period of eight months to complete them, and the inspection shall be conducted once again at the end of this period. The applicant may be granted a second grace period, which shall not exceed half of the initial grace period, namely four months. If it is proven afterwards that requirements are not fulfilled, the license application shall be finally rejected.

.....
In the event that the service has not been provided at the specified time, or some additional documents or fees are requested under any name whatsoever, you can contact one of the following official bodies: -
Governorate: Tel.

Administrative Control Authority: Headquarters in Cairo Tel: 02/2902727

Administrative Control Authority: Governorate Office Tel.

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{2} Appendix No. (6):-

Directorate of Health Affairs

Medical District

Pharmacy Department

Distinguished Major General/ Head of the neighborhood municipality

Greetings; to begin with,

Please kindly inform us about the status of the property in which the shop to be licensed is located.

.....
in the name of the pharmacist/, and that property's address is
.....

with regard to whether or not it has obtained a building permit, it is under state property, it is located in a squatter area, or it has received a removal decision. Please kindly inform us about the status of the shop to be licensed with regard to whether it is licensed as a commercial property, or as an apartment or as a garage.

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{3} Appendix No. (9):-

Governorate

Directorate of Health Affairs

Medical District

Pharmacy Department

A public pharmacy Inspection Record

- 1- Name of the license-requesting applicant/
- 2- His residential address/
- 3- The exact location of institution/
- 4- The type of required license/
- 5- Boundaries of the shop:- East/..... West/.....
South/..... North/
- 6- The inside lengths and height of the shop/
- 7- Surface Area /
- 8- The distance between the shop and the nearest pharmacy/.....
- 9- Opinion on the location/.....
- 10- Type of construction material and whether or not there is a building thereon/.....
- 11- Type of shop floor and ceiling material/.....
- 12- The area and type of its openings/

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- 13- Level of the shop floor in relation to the public road/.....
- 14- Water source/.....
- 15- Method of drainage/.....
- 16- How identical is the shop with the engineering layout/.....
- 17- Opinion on the fulfilment of health requirements /.....
- 18- If the requirements are not fulfilled, the applicant shall be notified and the grace period necessary for completing them shall be specified/.....
- 19- Date of the second inspection after the expiry of the initial grace period/.....
- 20- Result of the second inspection/.....
- Signatures of committee members:

The final opinion on the application shall be offered and the layout shall be signed and ratified:-

Manager of Pharmacy Department

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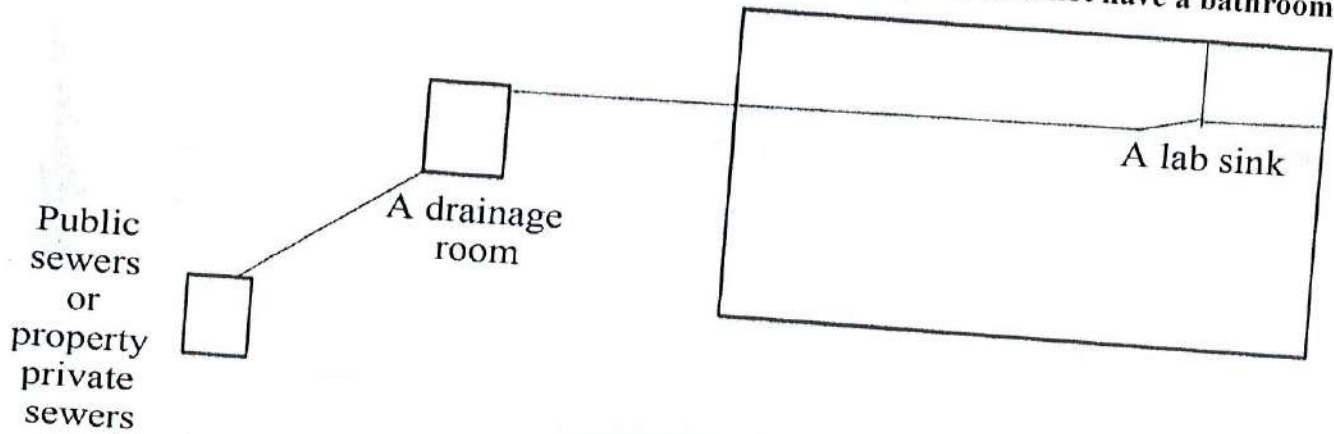
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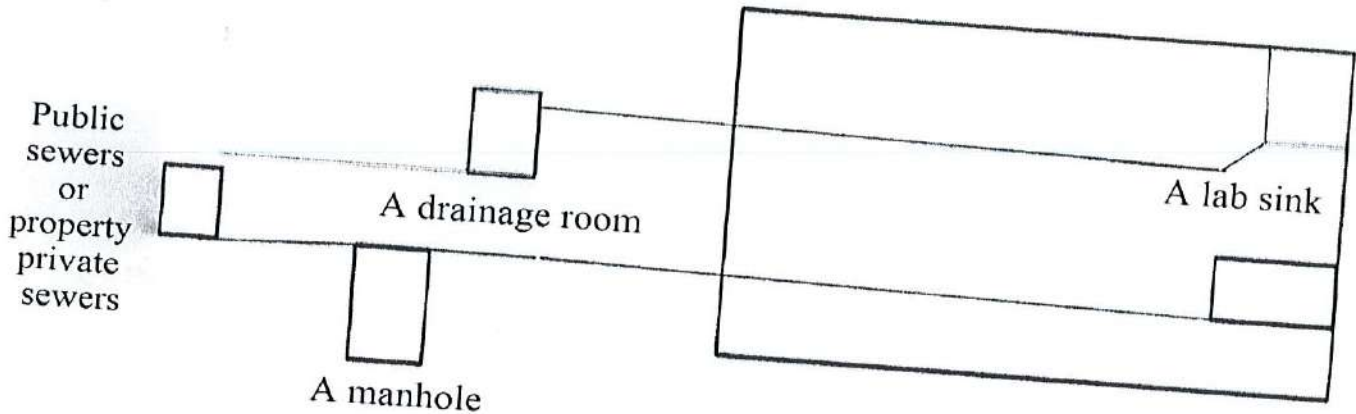
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{4} Appendix No. (13):-

A model of plan diagram showing the drainage of the pharmacy if it does not have a bathroom.



A model of plan diagram showing the sewage of the pharmacy if there is a bathroom.



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{5} Correction of errors in the numbers of some models attached to Decree No. (1) of 2010:-

* Correction of the number of Appendix No. (4) from number (4) to No. (11).

* Correction of the number of Appendix No. (11) from number (11) to No. (4).

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Third: Addition of the following procedures and controls:

- (1) In the case of licensing public pharmacies in commercial centers (shopping malls), the source of pure water may be the main water pipe of the commercial mall, the drainage may be with that of the rest of the stores in the mall, and the source of electricity may be from the mall's permanent public electricity source; nevertheless, documents proving these specifics must be submitted after being issued from the competent official authorities.
- (2) In the case of licensing a public pharmacy affiliated to one of the city authorities of the New Urban Communities Authority, the approval of the competent authority shall be required to allocate the activity of the shop for a public pharmacy.
- (3) Public pharmacies shall be licensed for the shops located in the buildings allocated for commercial centers (shopping malls), as well as for those inside the commercial corridors licensed for this purpose by the competent neighborhood municipality, taking into consideration that the stairs and commercial corridors are calculated within the distance required by law.
- (4) The applicant for a license for a private pharmacy attached to a private hospital shall submit the hospital license issued by the Department of Free Treatment at the Directorate of Health Affairs, and the said license shall demonstrate that the number of patient beds in the hospital are not less than forty beds.
- (5) In the case of a request to transfer the ownership of a public pharmacy, the pharmacist (buyer) shall submit an application to the competent pharmacy department requesting approval to transfer the ownership of the pharmacy concerned, and that application shall be accompanied by the following documents: -**
 - A contract of selling business assets of a pharmacy, including the assignment of the license; the said contract must be notarized by the real estate registry in accordance with an attestation report.
 - Birth certificate or any other document equivalent thereto.
 - A conviction-free criminal status record, issued to be submitted to the Department of Pharmacy at the competent Directorate of Health Affairs.
 - An identity verification certificate (a copy of a valid national ID or a copy of a valid passport).
 - A copy of the license to practice the profession of pharmacy, and a copy of ID card of the General Syndicate.
 - A certificate issued from the Central Administration for Pharmaceutical Affairs with regard to government-mandated internship to demonstrate that after his graduation, the pharmacist spent one year in practicing the profession of pharmacy in a governmental or a private institution.
 - A certificate issued from the Central Administration for Pharmaceutical Affairs at the Ministry of Health demonstrating the pharmacist's ownership or property share in public pharmacies.

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- A certificate issued by the General Syndicate stating that the pharmacist is registered in the General Syndicate's roll and that no disciplinary actions have been issued against him.
- A certificate issued by the subsidiary syndicate showing the approval for the trade name of the pharmacy.
- A notarized title or deed of the property licensed as a public pharmacy.
- The original license, the original engineering layout, and the books of the pharmacy to complete the notarization of the transfer of ownership and to prove the name of the new owner of the pharmacy thereon.

General Manager

General Directorate of Pharmaceutical Licensing
(signed)

(Dr. Azza Ahmed Yassin)

To be approved by
Chairman

Central Administration for Pharmaceutical Affairs
(signed)

(Prof. Tamer Mohamed Essam)